



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/678,960

10/03/2003

Karen Heins

3431.1003-000

7298

21005

7590

02/11/2008

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

530 VIRGINIA ROAD

P.O. BOX 9133

CONCORD, MA 01742-9133

EXAMINER

OLSEN, KAJ K

ART UNIT

PAPER NUMBER

1795

MAIL DATE

DELIVERY MODE

02/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/678,960	Applicant(s) HEINS ET AL.	
	Examiner KAJ K. OLSEN	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 1-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413) |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) ☒ Information Disclosure Statement(s) (PTO/SB/08) | 5) ☐ Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11-13-2007</u> . | 6) ☐ Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 1-35 remain withdrawn from further consideration.

Information Disclosure Statement

2. The examiner has lined through the citation of JP 11-326,275 because the examiner has already cited this document on the previous PTO-892 and its inclusion here is redundant. If applicant wishes to have the translation of this document to be on the record, then applicant should list this translation as being an "Other Document" on a future PTO-1449.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 36-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
5. Claims 36, 42, 48, and 51 have been amended to state that the device "does not alter the profile of the plate containing the sample". Applicant does not appear to have support for this

Art Unit: 1795

limitation. Although the specification states a number of times that the device has a “low profile” (p. 9, ll. 6-9; p. 13, ll. 18-20; and p. 18, ll. 18-20), this is not the same thing as not altering the profile as is currently being claimed. A low profile would presumably alter the profile to some extent in contrast to what the claims now state. Furthermore, fig. 3 would appear to contradict this new claim limitation because it appears to show the sample plate’s left edge resting on the base of the device. Hence, the embodiment of fig. 3 would appear to alter the profile because the base of the magnet plate would have some non-vanishing thickness that would be raising the plate containing the sample up by an amount proportional to the thickness of the device base.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 36-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Humphries et al (USP 6,954,128) with or without evidence from Kernan et al (USP 5,885,430).

8. Humphries discloses a device for applying a magnetic field to a sample that comprises one or more magnets (120, 130) attachable to a plate 110. See fig. 2 and col. 11, ll. 22-31. With respect to the device being insertable into either an electrophoretic apparatus or a nucleic acid

sequencer adjacent to a plate containing the sample, it is noted that this limitation doesn't appear to further define the actual device because whether or not the device is insertable into either an electrophoretic or sequencer apparatus adjacent a plate entirely depends on the structure of the unclaimed electrophoretic or sequencer apparatus and the plate. However, even if the examiner were to give these limitations further due consideration, it is noted that Humphries discloses placing the device adjacent a standard microtiter plate 210 for containing a sample. See fig. 8 and col. 24, ll. 20-25. Furthermore, Kernan discloses that electrophoretic apparatuses for DNA sequencing can be configured to accept standard microtiter plates. See fig. 1, col. 1, ll. 20-26, and col. 2, ll. 18-21. Hence, Kernan evidences that Humphries, when configured as a standard microtiter plate, would have been insertable inside an electrophoretic or sequencer apparatus like that of Kernan.

9. With respect to the new limitation that the device not alter the profile of the plate containing the sample, it is noted that the plate containing the sample is not part of the claimed invention, but is merely what the device for applying the magnetic field is to operate on. Hence, whether or not the device alters the profile of the plate containing the sample does not further limit the actual device itself. For example, it is noted that Humphries at its most basic level consists of a plate with magnets attached. Compare elements 110 and 130 of fig. 6B of Humphries with elements 14 and 12 of fig. 1 of the instant invention. They are structurally analogous. In the instant invention, the structure that presumably permits the device to not alter the profile of the plate containing the sample (however, see 112 rejection above) is a function of both the structure built around the device and the structure of the sample plate itself. For example looking at fig. 1 of the instant invention, the only way this structure would not alter the

Art Unit: 1795

profile of the plate containing the samples was if the plate containing the samples extending over the entire area of the device and this plate also had vertical “legs” that were at least as tall as the thickness of elements 16 and 18 combined when assembled. If the sample plate rests on top of element 18 of fig. 1, then the sample tray profile would have been altered. Because the sample plate is not being claimed, then this new limitation clearly doesn't further the device itself as it entirely depends on unclaimed and undisclosed details concerning the plate containing the samples.

10. Alternatively, if the examiner took the position that this new limitation does further define the structure of the device, it is noted that the device of Humphries does not alter the horizontal profile of the tray. See fig. 8 where the horizontal profile of the tray is the same as it would have been without the device. Because the claims do not specify any particular profile not to be altered, Humphries would not alter this particular profile and would thereby meet the claims.

11. With respect to the use of rare earth magnets, see Humphries, col. 8, ll. 48-51.

12. With respect to the sample being introduced into the sequencer by capillary electrophoresis, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability. However, see Humphries, col. 25, l. 50 through col. 27, l. 36.

13. With respect to the presence of magnetic microparticles, see Humphries, col. 25, l. 66 through col. 26, l. 5.

Art Unit: 1795

14. With respect to the electric field produced by the electrophoretic or sequencer apparatus, because applicant isn't claiming the electrophoretic or sequencer apparatus itself, this limitation does not further define the structure of the device.

15. With respect to the device being for applying a magnetic field during electrokinetic or physical injection into a nucleic acid sequencer, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.

Whether or not Humphries is utilized for direct injection of sample into a sequencer doesn't further define the actual device itself.

16. Claims 36-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al (USP 4,988,618) with or without evidence from Kernan. Li is being cited and relied on for the first time with this office action. Its use here was necessitated by applicant's amendment to the claims.

17. Li discloses a device for applying a magnetic field to a sample that comprises one of more magnets 5 attachable to a plate 1. See fig. 1 and col. 4, l. 63 - col. 5, l. 7. In addition, the device of Li would not alter the profile of the plate containing the sample because the device plate 1 is clearly the same dimensions as the sample plate (compare fig. 1 and 2) and the sample plate contains legs 22 that raise the sample plate off the ground. Furthermore, fig. 6B and 6C appear to show that the sample plate 42 is no higher than it would have been if the device were not being utilized. In particular, the legs of the sample plate appear to extend through the device and out the other side of the device (fig. 6B and 6C). In other words, the magnetic device did not make the sample plate any higher and thereby did not alter the profile for the sample tray. With respect to the device being insertable into either an electrophoretic apparatus or a nucleic acid

Art Unit: 1795

sequencer adjacent to a plate containing the sample, it is noted that this limitation doesn't appear to further define the actual device because whether or not the device is insertable into either an electrophoretic or sequencer apparatus adjacent a plate entirely depends on the structure of the unclaimed electrophoretic or sequencer apparatus and the plate. However, even if the examiner were to give these limitations further due consideration, it is noted that Li discloses utilizing the device with microtiter tray (see abstract) and Kernan discloses that electrophoretic apparatuses for DNA sequencing can be configured to accept standard microtiter plates. See fig. 1, col. 1, ll. 20-26, and col. 2, ll. 18-21. Hence, Kernan evidences that Li, when configured as a standard microtiter trays, would have been insertable inside an electrophoretic or sequencer apparatus like that of Kernan.

18. With respect to the use of rare earth magnets, see Li, col. 5, ll. 8-11.

19. With respect to the sample being introduced into the sequencer by capillary electrophoresis, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.

20. With respect to the presence of magnetic microparticles, see Li, col. 61-66.

21. With respect to the electric field produced by the electrophoretic or sequencer apparatus, because applicant isn't claiming the electrophoretic or sequencer apparatus itself, this limitation does not further define the structure of the device.

22. With respect to the device being for applying a magnetic field during electrokinetic or physical injection into a nucleic acid sequencer, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.

Whether or not Li is utilized for direct injection of sample into a sequencer doesn't further define the actual device itself.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. Claims 48-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Humphries or Li in view of Gombinski (USP 6,297,062).

25. As discussed above, Humphries and Li disclosed the set forth combination of the device as well as disclosed the use of magnetic microparticles. However, Humphries and Li did not explicitly disclose combining these two things into a kit. Gombinski teaches that a combination of magnetic microparticles and magnet matrix can be assembled together into a kit. See col. 15, l. 57 through col. 16, l. 10. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to combine the combination of magnetic microparticles and magnetic device of Humphries and Li into a kit as taught by Gombinski, so that the combination of elements can be readily made available for the operator. In addition, combining the magnetic device with the magnetic microparticles to be used with the device allows the magnetic strength of each of the particles and magnets to be uniquely tailored to each other to provide the most efficient immobilization scheme.

26. With respect to the additional reagents, see Humphries, col. 25, l. 66 - col. 26, l. 5 and Li, col. 7, ll. 51 - col. 8, l. 20.

Response to Arguments

27. Applicant's arguments filed 11-13-2007 have been fully considered but they are not persuasive. Applicant disagrees with the examiner's position that whether or not a device is insertable into an electrophoretic or sequencer apparatus entirely depends on the structure of the unclaimed electrophoretic or sequencer apparatus. In particular, they urged that the device of the instant invention is designed to have a low profile so that it can be disposed into the sequencer "without the need to reconfigure the sequencer" (arguments, p. 9, l. 3). However, this statement would appear to undermine the applicant's argument. If a sequencer can be reconfigured to accept a prior art magnetic plate, then this evidences that whether or not a device can be insertable into an electrophoretic apparatus or sequencer is in fact a function of that apparatus or sequencer. If the preexisting electrophoretic apparatus or sequencer has already been reconfigured to accept a prior art magnetic device, then that prior art device could be insertable into those electrophoretic apparatuses or sequencers. If the prior art electrophoretic apparatus had structure that was already not constrained by the profile of the prior art magnetic device, then that prior art magnetic device is also insertable into those electrophoretic apparatuses or sequencers. In either case, these limitations of claims 36, 42, 48, and 51 are a function of the structure of the electrophoretic apparatuses or sequencers themselves and not the device.

28. Applicant further urges that the sample plate in Humphries sits on top of the device and would substantially alter the profile of the microtiter plate. Again, whether or not the sample

plate sits on top of the device or extends over the device is a function of the unclaimed and unspecified sample plate. Applicant is only claiming the device and the structure of the sample plate to be utilized with the device does not further define the device itself.

29. Applicant further urges that the device of Humphries has a footprint that is slightly larger than a standard microtiter plate. It is unclear what the significance of this observation as the claims do not state anything about the footprint of the device. Moreover, the examiner cannot find anything in the specification that states that the footprint of the device of the instant invention is the same or smaller than the microtiter plate.

30. With respect to Kernan, applicant urges that Kernan does not evidence that the Humphries would be insertable into a electrophoretic or sequencer device because the device of Humphries substantially alters the profile of the sample plate. It is unclear what the significance of the altered profile would be for the apparatus of Kernan as Kernan does not appear to disclose anything that would seem to indicate that its device would be negatively affected by an altered profile for the sample trays. Fig. 10 shows that the particular tray being analyzed has to be raised up by lifting means 446 anyways (col. 12, ll. 35-42). An additional vertical profile to the sample tray would only means the lifting mechanism would have to lift the sample tray even less. Moreover, as the applicant already pointed out on p. 9, it was admitted that electrophoretic apparatuses and sequencers can be reconfigured to accommodate different sample plates.

31. Applicant's further arguments concerning the rejections relying on Gombinski appear to rely on the perceived failings of the earlier teaching of Humphries. Because those arguments were not persuasive as discussed above, these further arguments are similarly unpersuasive.

Conclusion

32. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAJ K. OLSEN whose telephone number is (571)272-1344. The examiner can normally be reached on M-F 7:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1795

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kaj K Olsen/
Primary Examiner, Art Unit 1795
February 12, 2008